

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

MEDERSKI, Werner et al.

Examiner: Shawquia Young

Serial No.: 10/561,227

Group Art Unit: 1626

Filed: December 19, 2005

Confirmation No.: 6157

Title: 1-[(4-ETHYNYLPHENYL)]-2-[(PHENYL)]-PYRROLIDINE-1,2-DICARBOXAMIDE DERIVATIVES AS INHIBITORS OF COAGULATION FACTORS XA AND VIIA FOR THE TREATMENT OF THROMBOSES

**RESPONSE TO REQUIREMENT FOR RESTRICTION**

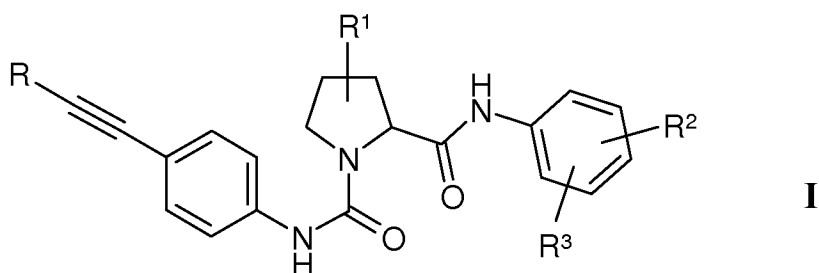
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The requirement for restriction mailed June 19, 2007, states that the list of groups is not exhaustive. Thus, applicants hereby elect a group not set forth therein, termed Group VIII, drawn to compounds of formula I wherein: R is as defined in Claim 1 excluding Het or Het-alkyl; R<sup>1</sup> is as defined in Claim 1 excluding Het or Het-alkyl; R<sup>2</sup> is H, Hal or A; R<sup>3</sup> is morpholinyl; X is aryl or arylalkyl; A is as defined in Claim 1; m is 1, 2, 3, 4, 5, or 6; and, n is 0, 1, 2, 3, 4, 5 or 6.

To the extent the examiner wishes an election of a single species, applicants elect the compound 1-[(4-ethynylphenyl)]-2-{[3-methyl-4-(3-oxomorpholin-4-yl)phenyl]}-(2R,4R)-4-methoxypyrrolidine-1,2-dicarboxamide which is disclosed in Example 1 on page 28, lines 24-25 (called "A-3"). The requirement for restriction is respectfully traversed.

The requirement for restriction is traversed for the following reasons. First, it is clear that all claims contain a "special technical feature," i.e., the formula I.



The backbone of Formula I, containing three rings and bridging portions exemplified, with optionally a fused ring, clearly is a substantial structure common to all compounds of the claims. In this regard, it is submitted that the Office Action misinterprets the PCT Rule 13.2. PCT Rule 13.2, as explained in annex B of the administrative instructions under the PCT, does *not* require **patentability**, based on the "special technical feature," for unity of invention. In the Markush situation, the rules specifically require *only* "common structure" or belonging to a "recognized class" of compounds. The only mention of novelty is the notation that, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention "shall be reconsidered." The instructions then state that reconsideration does *not* necessarily imply that an objection of lack of unity shall be raised.

It is thus evident that patentability over the art is *not* required in the Markush situation to establish unity of invention. Rather, the special technical feature need only possess common structure and a common property or activity. Common structure is evident, as noted above. Common properties are evident in that, as stated in the specification, at page 2, the compounds are all factor Xa inhibitors, and thus are useful to treat thromboembolic diseases. All of the claim compounds have a linked three-ring structure, with potentially one ring being fused, on an optional basis. It is not seen why the *entirety* of the structure is not being considered by the examiner. It is submitted that the structure as a whole presents the "special

technical feature" and that unity of invention is satisfied.

Moreover, with respect to groups V – VI, PCT Rule 13.2 and annex B state that, "in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the same product, and an independent claim for a use of the said product" ***shall be construed as having unity of invention.*** These rules, adopted in 37 CFR §1.475, clearly mandate that these groups of the present application be not restricted. 37 CFR §1.475(b) states that a National Stage Application containing claims to different categories of invention "will be considered to have unity of invention" if the claims are drawn only to one of various combinations of categories. One combination of category set forth is that discussed above: a product, a process specially adapted for the manufacture of the said product, and a use of the said product.

Accordingly, there is no legal basis to support the requirement for restriction, and withdrawal thereof is appropriate and is respectfully requested.

Respectfully submitted,  
\_\_\_\_\_  
/Harry B. Shubin/  
Harry B. Shubin, Reg. No. 32,004  
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-3112  
Date: July 19, 2007

HBS/cak